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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,941	05/05/2005	Isabel Climent-Johansson	13425-102US1	1422

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,941	CLIMENT-JOHANSSON ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 8, drawn to a protein complex comprising a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 2.

Group II, claim(s) 1, 3, 8, drawn to a protein complex comprising a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 3.

Group III, claim(s) 1, 4, 8, drawn to a protein complex comprising a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 4.

Group IV, claim(s) 1, 5, 8, drawn to a protein complex comprising a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 5.

Group V, claim(s) 1, 6, 8, drawn to a protein complex comprising a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 6.

Group VI, claim(s) 1, 7, 8, drawn to a protein complex comprising a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 7.

Group VII, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 2.

Group VIII, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 3.

Group IX, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 4.

Group X, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 5.

Group XI, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 6.

Group XII, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 7.

Group XIII, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 2.

Group XIV, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 3.

Group XV, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 4.

Group XVI, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 5.

Group XVII, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 6.

Group XVIII, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the polypeptide of SEQ ID NO: 7.

Group XIX, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 2.

Group XX, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 3.

Group XXI, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 4.

Group XXII, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 5.

Group XXIII, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 6.

Group XXIV, claim(s) 9, drawn to a method of modulating FOXC2 activity comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 7.

Group XXV, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 2.

Group XXVI, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 3.

Group XXVII, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 4.

Group XXVIII, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 5.

Group XXIX, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 6.

Group XXX, claim(s) 9, drawn to a method of modulating FOXC2 expression comprising contacting a cell expressing FOXC2 with the nucleic acid encoding the polypeptide of SEQ ID NO: 7.

Group XXXI, claim(s) 10-12, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 2.

Group XXXII, claim(s) 10-12, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 3.

Group XXXIII, claim(s) 10-12, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 4.

Group XXXIV, claim(s) 10-12, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 5.

Group XXXV, claim(s) 10-12, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 6.

Group XXXVI, claim(s) 10-12, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 7.

Group XXXVII, claim(s) 10, 13-14, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 2.

Group XXXVIII, claim(s) 10, 13-14, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 3.

Group XXXIX, claim(s) 10, 13-14, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 4.

Group XL, claim(s) 10, 13-14, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 5.

Group XLI, claim(s) 10, 13-14, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 6.

Group XLII, claim(s) 10, 13-14, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering to a patient the polypeptide of SEQ ID NO: 7.

Group XLIII, claim(s) 15, drawn to a method of identifying an agent that modulates the formation of a FOXC2 protein complex comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 2, in the presence of a candidate agent.

Group XLIV, claim(s) 15, drawn to a method of identifying an agent that modulates the formation of a FOXC2 protein complex comprising contacting a first polypeptide of SEQ

ID NO: 1 and a second polypeptide of SEQ ID NO: 3, in the presence of a candidate agent.

Group XLV, claim(s) 15, drawn to a method of identifying an agent that modulates the formation of a FOXC2 protein complex comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 4, in the presence of a candidate agent.

Group XLVI, claim(s) 15, drawn to a method of identifying an agent that modulates the formation of a FOXC2 protein complex comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 5, in the presence of a candidate agent.

Group XLVII, claim(s) 15, drawn to a method of identifying an agent that modulates the formation of a FOXC2 protein complex comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 6, in the presence of a candidate agent.

Group XLVIII, claim(s) 15, drawn to a method of identifying an agent that modulates the formation of a FOXC2 protein complex comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 7, in the presence of a candidate agent.

Group XLIX, claim(s) 16, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 2 in the presence of a candidate agent, and measuring a FOXC2 activity of the first polypeptide.

Group L, claim(s) 16, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 3 in the presence of a candidate agent, and measuring a FOXC2 activity of the first polypeptide.

Group LI, claim(s) 16, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 4 in the presence of a candidate agent, and measuring a FOXC2 activity of the first polypeptide.

Group LII, claim(s) 16, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 5 in the presence of a candidate agent, and measuring a FOXC2 activity of the first polypeptide.

Group LIII, claim(s) 16, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 6 in the presence of a candidate agent, and measuring a FOXC2 activity of the first polypeptide.

Group LIV, claim(s) 16, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 1 and a second polypeptide of SEQ ID NO: 7 in the presence of a candidate agent, and measuring a FOXC2 activity of the first polypeptide.

Group LV, claim(s) 17, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 2 with a candidate agent and contacting a second polypeptide of SEQ ID NO: 1 with the candidate agent.

Group LVI, claim(s) 17, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 3 with a candidate agent and contacting a second polypeptide of SEQ ID NO: 1 with the candidate agent.

Group LVII, claim(s) 17, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 4 with a candidate agent and contacting a second polypeptide of SEQ ID NO: 1 with the candidate agent.

Group LVIII, claim(s) 17, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 5 with a candidate agent and contacting a second polypeptide of SEQ ID NO: 1 with the candidate agent.

Group LIX, claim(s) 17, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 6 with a candidate agent and contacting a second polypeptide of SEQ ID NO: 1 with the candidate agent.

Group LX, claim(s) 17, drawn to a method of identifying an agent that modulates a FOXC2 activity comprising contacting a first polypeptide of SEQ ID NO: 7 with a candidate agent and contacting a second polypeptide of SEQ ID NO: 1 with the candidate agent.

Group LXI, claim(s) 18-20, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering an agent identified in Group XLIII.

Group LXII, claim(s) 18-20, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering an agent identified in Group XLIV.

Group LXIII, claim(s) 18-20, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering an agent identified in Group XLV.

Group LXIV, claim(s) 18-20, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering an agent identified in Group XLVI.

Group LXV, claim(s) 18-20, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering an agent identified in Group XLVII.

Group LXVI, claim(s) 18-20, drawn to a method for the treatment or prophylaxis of a medical condition treatable by increased FOXC2 activity comprising administering an agent identified in Group XLVIII.

Group LXVII, claim(s) 18, 21-22, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering an agent identified in Group XLIII.

Group LXVIII, claim(s) 18, 21-22, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering an agent identified in Group XLIV.

Group LXIX, claim(s) 18, 21-22, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering an agent identified in Group XLV.

Group LXX, claim(s) 18, 21-22, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering an agent identified in Group XLVI.

Group LXXI, claim(s) 18, 21-22, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering an agent identified in Group XLVII.

Group LXXII, claim(s) 18, 21-22, drawn to a method for the treatment or prophylaxis of a medical condition treatable by decreased FOXC2 activity comprising administering an agent identified in Group XLVIII.

Group LXXIII, claim(s) 23, drawn to a method for purifying a FOXC2-interacting protein comprising contacting a protein complex comprising a FOXC2 protein of SEQ ID NO: 1 and a FOXC2-interacting protein of SEQ ID NO: 2 with an antibody that binds to the protein complex.

Group LXXIV, claim(s) 23, drawn to a method for purifying a FOXC2-interacting protein comprising contacting a protein complex comprising a FOXC2 protein of SEQ ID NO: 1 and a FOXC2-interacting protein of SEQ ID NO: 3 with an antibody that binds to the protein complex.

Group LXXV, claim(s) 23, drawn to a method for purifying a FOXC2-interacting protein comprising contacting a protein complex comprising a FOXC2 protein of SEQ ID NO: 1 and a FOXC2-interacting protein of SEQ ID NO: 4 with an antibody that binds to the protein complex.

Group LXXVI, claim(s) 23, drawn to a method for purifying a FOXC2-interacting protein comprising contacting a protein complex comprising a FOXC2 protein of SEQ ID NO: 1 and a FOXC2-interacting protein of SEQ ID NO: 5 with an antibody that binds to the protein complex.

Group LXXVII, claim(s) 23, drawn to a method for purifying a FOXC2-interacting protein comprising contacting a protein complex comprising a FOXC2 protein of SEQ ID NO: 1 and a FOXC2-interacting protein of SEQ ID NO: 6 with an antibody that binds to the protein complex.

Group LXXVIII, claim(s) 23, drawn to a method for purifying a FOXC2-interacting protein comprising contacting a protein complex comprising a FOXC2 protein of SEQ ID NO: 1 and a FOXC2-interacting protein of SEQ ID NO: 7 with an antibody that binds to the protein complex.

The inventions listed as Groups I-LXXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention is lacking since it appears no common special technical feature exists between Groups I-LXXVIII. For instance, Groups 1-6 are drawn to completely different products, in the instant case, different protein complexes. Groups 7-12, 13-18, 19-24, and 25-30 are drawn to different methods of modulating FOXC2 with different products, in the instant case, different polypeptide sequences and the nucleic acids encoding the different polypeptide sequences. Furthermore, while Groups 31-36, 37-42, 61-66, and 67-72 are drawn to methods for the treatment of a medical condition treatable by modulated FOXC2 activity, the conditions are differentiated by increased or decreased FOXC2 activity, and comprise the administration of completely different products. Groups 43-48 are drawn to a different method than Groups 49-54 and 55-60 and

involve different candidate agents. Finally, Groups 73-78 are drawn to a method of purifying a FOXC2-interacting protein involving different antibodies. Therefore, unity of invention is lacking since no common special technical feature exists between Groups I-LXXVIII.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 25, 2006

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER